

REMARKS

I. Status Summary

Claims 1, 3-6, 16-20, 22-25, 33-39, and 41-44 are pending in the present U.S. patent application. Claims 3, 6, 17, 22, 25, 33-39, and 41-44 currently stand withdrawn. Claims 1, 4, 16, 18-20, and 23 have been examined by the United States Patent and Trademark Office (hereinafter "the Patent Office") in a Final Official Action dated December 12, 2011 (hereinafter the "Official Action") and presently stand rejected.

Claims 1, 4, 16, 18-20, and 23 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1199080 to Bauer et al. (hereinafter "Bauer") in view of Finkelman et al. (*J. of Immunology*, 151, 1235-1244 (1993); hereinafter "Finkelman"). In addition, claims 5 and 24 have been made the subject of an objection.

Claim 16 has been cancelled. Claims 1, 5, 18 and 24 have been amended. Support for the amendments can be found in the application as filed. No new matter has been added.

Reconsideration of the application as amended and in view of the remarks presented herein below is respectfully requested.

II. Response to Rejection under 35 U.S.C. Section 103(a) over Bauer in view of Finkelman

Claims 1, 4, 16, 18-20, and 23 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bauer in view of Finkelman. The Patent Office contends that Bauer teaches treatment with a human IL-3 mutant protein to treat immune thrombocytopenia and that the IL-3 mutant protein constitutes a "foreign antigen." The Patent Office concedes that Bauer does not teach administration of the protein in the form of a complex with an anti-IL-3 antibody. However, the Patent Office contends that Finkelman teaches that IL-3 administered in the form of a complex of IL-3 with an anti-IL-3 antibody results in enhanced IL-3 activity and increased half life *in vivo* in comparison to administration of IL-3 alone.

After careful consideration of the rejection and of the Patent Office's comments, applicants respectfully traverse the rejection and offer the following remarks.

Initially, applicants respectfully submit that claim 1 has been amended herein to recite "wherein the antibody and the antigen fail to treat immune thrombocytopenia." Support for the amendment can be found in the instant specification as filed, for example at page 14, lines 23-26 which describes that neither the antigen OVA by itself nor any anti-OVA antibodies by themselves affect platelet count or inhibit immune thrombocytopenia. In addition, claim 1 has been amended to recite "an effective amount of an IgG antibody" and "said antibody-antigen conjugate treats immune thrombocytopenia in the mammal expressing the Fc γ RIIB receptor." Support for the amendments can be found in claim 1 as originally filed and in the instant specification, for example at page 14, lines 17-19.

In view of the amendment to claim 1, claim 16 has been cancelled. Accordingly, the rejection with regard to claim 16 has been rendered moot.

Claim 18 has been amended to recite "wherein the antibody and the antigen fail to inhibit platelet clearance." Claim 18 has also been amended to recite "a therapeutic amount of an IgG antibody." Support for the amendment can be found in original claim 18 and in the instant specification at page 14, lines 23-26.

Applicants respectfully submit that to support a conclusion of obviousness: (a) all the claimed elements should be known in the art; (b) one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions; and (c) the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. See Manual of Patent Examining Procedure (hereinafter "MPEP") § 2143.02.

Applicants respectfully submit that as described above, instant claims 1 and 18 have been amended to indicate that neither the antigen nor the antibody have the ability to treat immune thrombocytopenia (ITP) or to inhibit platelet clearance, but that the antibody-antigen conjugate is able to treat ITP or inhibit platelet clearance. Claims 4, 19, 20 and 23 each depend from either claim 1 or 18. Applicants respectfully submit that the presently claimed subject matter relates to the surprising showing, described in the instant specification, that the formation of an immune complex between a soluble antigen which does not treat ITP nor inhibit platelet clearance and its respective antibody (which also does not treat ITP nor inhibit platelet clearance) is beneficial for the

treatment of ITP, as well as for inhibiting platelet clearance. For example, the instant specification describes that neither the antigen OVA nor anti-OVA antibody alone have the ability to treat ITP and/or affect platelet count. However, the combination of OVA and an anti-OVA antibody was essentially as successful at inhibiting ITP as a standard dose of IVIg. See Instant Specification, page 14, lines 17-26 and Figures 3A-3C.

The Patent Office contends that Bauer teaches that a human IL-3 mutant protein can treat ITP. See Office Action, point 8. The Patent Office further contends that it would be obvious to provide an antigen-antibody complex of IL-3 because Finkelman teaches that administering IL-3 in the form of a complex enhances IL-3 activity and increases half life *in vivo*. However, applicants respectfully submit that the cited combination, either alone or in combination, do not teach or suggest forming an antibody complex of an antigen and an antibody that individually fail to exhibit therapeutic activity to treat ITP or inhibit platelet clearance.

Accordingly, applicants respectfully submit that the presently disclosed and claimed subject matter is distinguishable over Bauer and Finkelman, either alone or in combination. Applicants respectfully request that the rejection of claims 1, 4, 18-20, and 23 under 35 U.S.C. § 103(a) over Bauer and Finkelman be withdrawn and further request that claims 1, 4, 18-20, and 23 be allowed at this time.

III. Response to Claim Objections

Claims 5 and 24 have been objected to as being dependent upon a rejected base claim. The Patent Office has indicated that claims 5 and 24 would be allowable if rewritten in independent form.

Applicants gratefully acknowledge the Patent Office's indication regarding the allowability of the subject matter of claims 5 and 24. Applicants respectfully submit that claims 5 and 24 have been amended to independent form. Support for the amendments can be found in claims 1, 5, 18, and 24 as previously pending. Additional support can be found in the PCT application as originally filed at page 2, line 20 and lines 28-32; at page 4, line 17; at page 6, line 25; at page 7, lines 14-16; at page 13, line 28 to page 14, line 1; at page 18, lines 7-9; and in Figures 3A-3C, 6A, and 6B.

Accordingly, applicants respectfully request the withdrawal of the instant objections. Applicants further respectfully request the allowance of claims 5 and 24 at this time.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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